REMARKS/ARGUMENTS

Favorable reconsideration of this application, as presently amended and in light of the following discussion, is respectfully requested.

Claims 19-35 and 37-38 are currently pending, Claims 19-35 having been amended, and Claims 37-38 having been added. The changes and additions to the claims do not add new matter and are supported by the originally filed specification, for example, on page 6, lines 13-18, page 7, lines 12-13, page 10, lines 10-17, and page 11, line 12 to page 12, line 2, and in Figure 3A.

In the outstanding Office Action, Claims 19-24 and 28-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Fischer et al. (U.S. Patent No. 5,646,046, hereinafter "Fischer"); and Claims 19-36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Burns et al. (U.S. Patent App. Pub. No. 2003/0054542, hereinafter "Burns").

Applicant wishes to thank Examiner Handy for the courtesy of an interview with Applicant's representatives, Mr. Tyson Crane and Mr. Sameer Gokhale, on August 9, 2010. During the interview, Applicant's representatives explained the claimed features of the present invention and discussed the differences between the claims and the applied reference. Clarifying amendments to the claims were further discussed. Claims and arguments similar to those discussed during the interview are presented below for formal consideration.

With respect to the rejections of Claim 1 under 35 U.S.C. §§ 102(b) and 102(e), Applicant respectfully submits that the amendment to Claim 1 overcomes these grounds of rejection. Amended Claim 1 recites,

> A blood analyzer for analyzing whole blood which includes a quality control device, said blood analyzer comprising:
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> means for analyzing patient blood samples;
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> a quality control device including,
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> means for storing by refrigeration control bloods,

means for restoring the control bloods to a temperature prescribed by a manufacturer of the control bloods,

means for stirring the control bloods for re-suspension of cells, and

means for sampling the control bloods.

Fischer describes an automated analyzer and method used for testing blood samples in the clinical laboratory for thrombosis and hemostasis properties.[1] In Fischer the sample handling system includes a refrigerated housing 26 for storing a plurality of evacuated collection tubes, and a piercer 34 for piercing an evacuated collection tube allowing a sample probe to be lowered into the sample collection tube. Fischer explains that the refrigerated housing 26 also stores a plurality of reagent probes 38, 40, and 42 which can be accessed by reagent probes 38, 40, and 42.[2]

In addition, Fischer describes that reagent quality is insured by an on-board control program and an assay specific quality control program which employs statistical rules with the ability to detect errors in the reagents.[3] Fischer explains that the system quality control defaults to a new control run mode when the allotted time designated for the control run frequency is reached.[4]

The Office Action apparently asserts that the refrigerated housing 26 and Peltier device of Fischer correspond to the means for storing and means for restoring of Claim 1, and that the sample probe 36 and plurality of reagent probes of Fischer correspond to the means for sampling of Claim 1.

However, Applicant respectfully submits that Fischer fails to disclose or suggest at least ***a blood analyzer*** including means for analyzing ***patient blood samples***, and ***a quality***

[1] Fischer, Abstract.
[2] *Id.* at col. 9, ll. 19-52.
[3] *Id.* at col. 8, l. 62 to col. 9, l. 7.
[4] *Id.* at col. 22, ll. 44-67.

control device including means for storing by refrigeration ***control bloods***, means for restoring the ***control bloods*** to a temperature prescribed by a manufacturer of the ***control bloods***, means for stirring the ***control bloods*** for re-suspension of cells, and means for sampling the ***control bloods***. By contrast, Fischer merely describes a sample handling system for blood samples including a refrigerated housing 26, a sample probe 36, and a plurality of reagent probes. In other words, Fischer merely describes a system for sample blood. Thus, even if we were to assume that system of Fischer corresponds to the means for analyzing patient blood samples, Fischer fails to disclose or suggest a separate quality control device for control bloods.

Burns describes an automated analyzer for performing multiple diagnostic assays simultaneously, and includes stations for preparing a specimen sample, incubating the sample at a prescribed temperature, performing an analyte isolation procedure, and ascertaining the presence of a target analyte.[5] Burns explains that an automated receptacle transporting system moves the reaction receptacles from one station to the next.[6] Burns also describes a computer controller which runs the assay manager program software.[7] In addition, Burns describes a cooling bay 900, incubators 600, 602, 604, and 606, and pipette assemblies 450 and 470.

The Office Action asserts that the reagent cooling bay 900 and incubators 600, 602, 604, and 606 of Burns corresponds the means for storing of Claim 1, the Peltier device of Burns corresponds to the means for restoring of Claim 1, and the pipette assemblies 450 and 470 correspond to the means for sampling of Claim 1.

However, Applicant respectfully submits that Burns fails to disclose or suggest at least ***a blood analyzer*** including means for analyzing ***patient blood samples***, and ***a quality control device*** including means for storing by refrigeration ***control bloods***, means for

[5] Burns, Abstract.
[6] *Id.*
[7] *Id.* at [0100].

restoring the ***control bloods*** to a temperature prescribed by a manufacturer of the ***control bloods***, means for stirring the ***control bloods*** for re-suspension of cells, and means for sampling the ***control bloods***. By contrast, Burns merely describes an automated analyzer which includes a reagent cooling bay 900 and incubators 600, 602, 604, and 606, a Peltier device, and pipette assemblies 450 and 470 for specimen samples. In other words, Burns merely describes a system for specimen samples. Thus, even if we were to assume that system of Burns corresponds to means for analyzing patient blood samples, Burns fails to disclose or suggest a separate quality control device for control bloods.

Thus, Applicant respectfully submits that amended Claim 1 (and all associated dependent claims) patentably distinguishes over Fischer and Burns.

With respect to the rejection of Claim 25 under 35 U.S.C. § 102(e) as anticipated by Burns, Applicant respectfully transverses this ground of rejection in part and further submits that the clarifying amendment to Claim 25 overcomes this ground of rejection. Amended Claim 25 recites, *inter alia*,

> wherein the means for stirring includes the tube support articulated about a hinge of the refrigeration block and configured to operate by inverting.

The Office Action asserts that the orbital mixer of Burns corresponds to the means for stirring of Claim 25.

However, Applicant respectfully submits that Burns fails to disclose or suggest that the means for stirring includes ***the tube support articulated about a hinge of the refrigeration block*** and ***configured to operate by inverting***. By contrast, Burns merely describes, in reference to Figures 32-34, an orbital mixer 552 including an MTU carrier 558 and moves the MTU carrier in an orbital path to agitate the contents of the MTU. Thus, even if we were to assume that the orbital mixer of Burns corresponds to the means for stirring of

Claim 25, the orbital mixer of Burns does not include ***a tube support articulated about a hinge of the refrigeration block*** and ***configured to operate by inverting***.

Thus, Applicant respectfully submits that amended Claim 25 patentably distinguishes over Burns.

In addition, Applicant respectfully submits that new Claim 37 recites further features that are not disclosed or suggested by the applied references. New Claim 37 recites that the quality control device further includes a triggering unit which triggers a quality control procedure to determine whether the analyzer is functioning properly based on a comparison using the control bloods. By contrast, Fischer merely describes an on-board control program and assay specific quality control program to detect errors in the reagents, and Burns merely describes a computer controller that runs the analyzer described above. Thus, Fischer and Burns fail to disclose or suggest at least a ***quality control device*** which includes a triggering unit which triggers ***a quality control procedure*** to determine whether the analyzer is functioning properly based on a comparison ***using the control bloods***.

Consequently, in light of the above discussion and in view of the present amendment, the outstanding grounds for rejection are believed to have been overcome. The present application is believed to be in condition for formal allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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